K080992

SEP - 4 2008

510(k) SUMMARY (as required by 21 CFR 807.92)

High Tibial Osteotomy (HTO) Plating System
April 7, 2008

COMPANY: Aesculap Implant Systems, Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 2916714

CONTACT: Lisa M. Boyle
(610) 984-9274 (phone)
610-791-6882 (fax)

TRADE NAME: HTO Plating System

COMMON NAME: High Tibial Osteotomy (HTO) Plating System

CLASSIFICATION NAME: Plate, Fixation, Bone (HRS)
Screw, Fixation, Bone (HWC)

REGULATION NUMBER: 888.3030 / 888.3040

SUBSTANTIAL EQUIVALENCE

Aesculap Implant Systems, Inc., believes that the HTO Plating System is substantially equivalent to the Arthrex Puddu Osteotomy System (K973812).

DEVICE DESCRIPTION

The Aesculap Implant Systems High Tibial Osteotomy (HTO) Plating System which consists of a single tapered plate, screws (cancellous and cortical design), and spacer blocks in various sizes. The plate in this system accepts 6 mm cancellous screws proximally and 4.5 mm cortical screw distally. The Aesculap Implant Systems High Tibial Osteotomy (HTO) Plating System is manufactured from Titanium/Titanium Alloy and will be provided sterile.

INDICATIONS FOR USE

The Aesculap Implant Systems High Tibial Osteotomy (HTO) Plating System is intended to be used in conjunction with bone screws to provide fixation following Proximal Tibial opening wedge osteotomies.

TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))

The Aesculap Implant Systems HTO Plating System is considered substantially equivalent to other legally marketed predicate systems. Biomechanical testing of the subject device was found to be similar in performance to previously cleared high tibial osteotomy systems with similar indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Aesculap Implant Systems, Inc.
% Ms. Lisa M. Boyle
Senior Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

SEP - 4 2008

Re: K080992
Trade/Device Name: High Tibial Osteotomy (HTO) Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, HWC
Dated: August 5, 2008
Received: August 5, 2008

Dear Ms. Boyle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

A. INDICATIONS FOR USE STATEMENT

510(k) Number: K080992

Device Name: **Aesculap Implant Systems High Tibial Osteotomy (HTO) Plating System**

Indications for Use:

The Aesculap Implant Systems High Tibial Osteotomy (HTO) Plating System is intended to be used in conjunction with bone screws to provide fixation following Proximal Tibial opening wedge osteotomies.

Prescription Use X and/or Over-the-Counter Use ______
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buehler for MXM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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